Conf. No: **1452** June 27, 2003

## **REMARKS**

Claims 1-2 and 4 are pending in this application.

Claims 1-4 have been rejected.

Claim 3 has been cancelled without prejudice. Claim 1 has been amended to incorporate the limitations of claim 3. Claims 1, 2 and 4 have been amended to more clearly set forth the present invention. Support for claims 1, 2 and 4 as amended appears in the specification, at page 4, lines 6-7, page 7, lines 6-15, pages 15-17, and 23-25. No new matter has been added.

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

I. At page 2 of the Office Action claims 1-4 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking written description.

The Examiner states that with respect to the method by which the concentrations of the cyclic ester compounds and cyclic urethane compounds are determined, it is unclear to what extent the films, bonded by the adhesive must be controlled or limited. The Examiner states that it is unclear if the results are accurate or repeatable regardless of the composition of the films. For example, the Examiner states that it is unclear to what extent the results would be affected if polyester films, derived from an acid other than naphthalenedicarboxylic acid, were bonded by the adhesive and tested. The Examiner also states it is unclear what effect would result if the films, bonded with instant adhesive, were derived from naphthalenedicarboxylic acid. In view of the following, this rejection is believed to be overcome.

Claims 1 and 4 have been amended to clearly set forth the method by which the concentrations of the cyclic ester compounds and the cyclic urethane compounds, are determined. Specifically, claims 1 and 4 have been amended to recite "...compounds extracted from a volume of water, and eluted from the laminate adhesive through a composite film bonded with the laminate adhesive into the volume of water, where the volume of water is equivalent to 0.5mL/cm<sup>2</sup> of the composite film,

Conf. No: 1452 June 27, 2003

are present at a concentration of 0.5ppb or less per 0.5mL/cm<sup>2</sup> of the composite film, are determined by gas chromatograph-flame ionization using dibutyl phthalate as a reference compound".

We note that the revised PTO guidelines concerning compliance with the written description requirement, state that: "an adequate description may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention."

The present specification includes the claims as originally filed. The rejected claims, are as originally filed. It is submitted that the skilled artisan would readily recognize that Applicant's were in possession of the claimed invention, based on the described required property, i.e., concentration of cyclic ester or urethane compounds eluted from the laminate adhesive.

The specification clearly states in the paragraph bridging pages 4 and 5, that the laminate adhesive of the present invention elutes cyclic ester compounds into the content of whatever is packaged by the composite film, in an amount that is significantly reduced as compared to the amount of cyclic ester compounds eluted by urethane based adhesives.

Pages 23 and 25 of the present specification describe the production of a composite film, and elution tests of that composite film. In the description, a composite film is prepared using the present laminate adhesive to bond the film layers into the composite film. The bonded films were cured to produce a composite film. Thereafter, a bag was made from each of the composite films produced and filled with water in an amount of  $0.5 \text{mL/cm}^2$  per unit area of the interior surface of the bag. The bag was then heat sterilized under pressure for 30 minutes. The water contained in the bag was then extracted and samples were drawn from the extracts. The samples were tested for the presence of cyclic ester compounds and cyclic urethane compounds, using gas chromatography (flame ionization). The structure of the eluting substance was analysized using dibutyl phthalate as the reference compound. The specification at page 24 states that the detection limit of the gas chromatograph for dibutyl phthalate was 0.5 ppb per  $0.5 \text{mL/cm}^2$  of composite film.

Conf. No: 1452 June 27, 2003

It is submitted that the present specification clearly sets forth the method by which the concentration of cyclic ester compounds and cyclic urethane compounds, are determined. It is further clear that the origination of such cyclic ester compounds and cyclic urethane compounds lies with the adhesive, and not with the film layers of the composite film, according to the claims as amended.

Regarding the Examiner's concerns about the effects of various film compositions, regardless of the composition of the film, the claims require that a concentration of eluted cyclic compounds be at or less than the claimed amount (limit of detection). If such compounds are present at a concentration above the claimed amount, the adhesive does not fall within the claim.

In view of the above, it is submitted that claims 1, 2, and 4 are clear and definite within the meaning of 35 U.S.C. § 112, 2<sup>nd</sup> paragraph. It is further submitted that claims 1, 2 and 4, are adequately described such that one of ordinary skill in the art can readily make and use the claimed invention, and that the disclosure at the time the application was originally filed, clearly conveys to the skilled artisan that the inventor had possession of the claimed subject matter, within the meaning of 35 U.S.C. § 112, 1<sup>st</sup> paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

## II. At pages 2 and 3 of the Office Action, claims 1, 2 and 4 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Goto et al. (820).

The Examiner states that Goto disclose polyurethane laminate adhesive compositions including a polyester polyol, derived from naphthalenedicarboxylic acid. The Examiner points to columns 2, 3, and 7, as well as the examples, in support of his position. The Examiner concludes that since the polyurethane is derived from a polyester polyol that meets the polyester polyol claim limitation recited by Applicants, the position is taken that the claimed concentrations of cyclic compounds are inherent characteristics of the disclosed composition. In view of the following, this rejection is believed to be overcome.

Conf. No: 1452 June 27, 2003

Goto is directed to a thermoplastic polyamide urethane urea resin fully retaining, or occasionally having improved adhesiveness, bonding ability, water resistance, and dry cleaning resistance. The resin includes (A) a linear polyhydroxyl oligomer having at both terminals one hydroxyl group each of which is free from ethylene terephthalate, (B) a linear polyester oligomer having one hydroxyl group each at both terminals consisting of ethylene terephthalate and ethylene naphthalene, (C) a linear polyamide oligomer, and (D) an organic diisocyanate. The polyhydroxyl oligomer (A) used in examples 1-3 and 5-7 of Goto (with the exception of example 4 which uses PTMG, and is not a polyester) are; PEPA, PEA, PNHA, and PBA, respectively. Specifically, the polyhydroxyl oligomers used in examples 1-3 and 5-7 are esters of adipic acid.

Goto does not teach or suggest a resin composition free from adipic acid. Claim 1 as amended recites that the acid component "...consists of naphthalenedicarboxylic acid, and optionally a dimer acid and/or phthalic acid...", thereby excluding adipic acid.

Further, claim 1 requires that a concentration of eluted cyclic ester compounds be below 0.5 ppb or less per 0.5mL/cm<sup>2</sup> (the detection limit). Goto does not teach or suggest a composition where a concentration of eluted cyclic ester compounds is at or below 0.5 ppb or less per 0.5mL/cm<sup>2</sup>. Specifically, examples 1-3 and 5-7 of Goto, all include esters of adipic acid. The use of esters of adipic acid result in the elution of cyclic ester compounds above the claimed amount (the detection limit), as shown in the Declaration submitted herewith. Please see the discussion of the Declaration, set forth below.

In view of the above, it is submitted that Goto et al. does not teach each and every element of the claimed invention as required for anticipation under 35 U.S.C. § 102(b). Thus, the Examiner is respectfully requested to withdraw this rejection.

Conf. No: 1452 June 27, 2003

III. At page 3 of the Office Action, claim 3 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Goto et al. in view of Pinfold et al. or WO 93/24551.

The Examiner states that Goto discloses polyurethane laminating adhesive compositions including a polyester polyol derived from naphthalenedicarboxylic acid. The Examiner states that Goto further discloses that additional acid species may be incorporated within the polyester polyol; however, Goto is silent regarding the specific use of a dimer acid. The Examiner states that dimer acid is a known acid reactant for the production of polyester polyols, suitable for use in the production of polyurethane adhesives, as supported by Pinfold. The Examiner concludes that it would have been obvious to utilize dimer acid as an additional acid reactant for producing the polyester polyol of the primary reference, because it has been held that it is obvious to utilize a known compound for its known function. In view of the following, this rejection is believed to be overcome.

A brief analysis of Goto is set forth above. Pinfold is directed to heat-softenable polyurethane adhesives. These adhesives are produced by reacting a diisocyanate and a polyester glycol including terephthalic acid and hexane diol 1, 6 units. Pinfold discloses that dimer acids may be used for the acid component, as well as adipic acid. Pinfold does not distinguish between the two acids and teaches that either are suitable.

WO 93/24551 is directed to aqueous polyurethane dispersions including a dimer based polyester polyol. Example 1 discloses the use of adipic acid. As discussed above, the use of adipic acid results in the elution of cyclic ester compounds.

Claim 1 of the present invention has been amended to require that the acid component of the polyester polyol consists of naphthalenedicarboxylic acid, and optionally a dimer acid and/or phthalic acid. Claim 1, as amended to recite the transition language "consists of", thereby excludes adipic acid. Claim 3 has been cancelled without prejudice.

The use of esters of adipic acid result in an elution of the cyclic compounds of the adipic acid and the glycol. In support of the foregoing, and filed herewith, please find a Declaration under 37

Conf. No: 1452 June 27, 2003

CFR § 1.132, submitted in co-pending patent application Serial No. 09/626,913, which evidences the presence of cyclic compounds eluting from a composite film containing an ester of adipic acid.

The subject Declaration illustrates the preparation of an aqueous polyurethane polymer dispersion where a polyurethane prepolymer was first prepared using an ester of adipic acid. Once the prepolymer was prepared, it was dispersed in water and hydrazine was added to effect chain extension, thereby producing the aqueous polyurethane polymer dispersion.

A composite film was then produced using the prepared polymer dispersion as the adhesive. The laminated adhesive was applied onto an aluminum surface of the two layered composite film including a polyethylene terephthalate film layer and an aluminum foil layer. The bonded film was cured, and a bag was made from the cured composite film. Elution tests, as outlined on page 3 of the Declaration, were performed. As can be seen from page 4 of the Declaration, a substance was identified, eluting from the adhesive through the film, as a cyclic ester compound of adipic acid, and 1, 6-hexandiol produced by the reaction of adipic acid and glycol.

In view of the foregoing, the use of esters of adipic acid in resins/adhesives results in an elution of cyclic compounds produced by the reaction of adipic acid and glycol.

Goto teach the use of a resin including esters of adipic acid as the polyhydroxyl oligomer (A). Goto does not teach or suggest a polyester resin composition absent adipic acid, as required by the present claims. Goto does not teach or suggest a composition that reduces elution of cyclic compounds. The Declaration filed herewith, establishes that the use of esters of adipic acid results in the elution of cyclic compounds from the resin. Claim 1 as amended, excludes adipic acid, and requires that a concentration of eluted cyclic ester compounds, be at or below 0.5 ppb or less per 0.5mL/cm<sup>2</sup> (the detection limit).

Pinfold does not cure the deficiencies of Goto, since Pinfold does not provide any motivation to modify the composition of Goto to exclude adipic acid, as required by the present claims. In fact, Pinfold teaches that dimer acids and adipic acids are equivalent, and both are equally suitable for use.

Conf. No: 1452 June 27, 2003

Pinfold does not teach or suggest a composition which results in reduced elution of cyclic compounds from the composition, as required by the present claims.

WO 93/24551 does not cure the deficiencies of either Goto or Pinfold, taken alone or together, since this reference also does not provide any motivation to modify the composition of Goto and/or Pinfold, to exclude adipic acid. WO 93/24551 exemplifies the use of adipic acid. This reference does not teach or suggest a composition which results in the reduced elution of cyclic ester compounds from the composition, as required by the present claims.

It is critical to exclude adipic acid from the present adhesive laminate, in order to achieve the claimed composition having the new and unexpected result of reduced elution of cyclic compounds, reduced to a concentration at or below the claimed concentration, which claimed concentration is the limit of detection. The Declaration evidence submitted herewith and discussed above, establishes that compositions including adipic acid do not possess the claimed critical property of reduced elution to at or below the claimed concentration.

None of the cited references, taken alone or together, teach or suggest the critical property of reduced elution to at or below the claimed concentration, as required by the present claims.

In view of the foregoing, it is submitted that nothing in any of the cited references, taken alone or together, render the claimed invention obvious within the meaning of 35 U.S.C. § 103(a). Thus, the Examiner is respectfully requested to withdrawn this rejection.

Conf. No: 1452 June 27, 2003

In view of the foregoing amendments and remarks, it respectfully requested that the application is in condition for immediate allowance. Early notice to that effect is solicited.

If the Examiner has any questions regarding this Amendment, the application is general, or has any suggestions for placing the application in condition for allowance, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully submitted,

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